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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51US11	8878

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,763

Applicant(s)

THOMPSON ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23, 25, 26 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 14, 17-21, 23, 25, 26 and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,168,617 to Blaeser et al.

Blaeser discloses a catheter with a stent (48) mounted on a distal region of a shaft (14) and a retractable sheath (28). Figure 4 shows that apertures (52) may be formed in the outer sheath (column 6, lines 9-10), and a port (60) is in communication with a passageway in the catheter and the apertures of the outer sheath (column 5, lines 30-32 and 50-54). Some of the apertures may be located proximal or distal to the "stent mounting location", since the sheath (28) extends past both ends of the stent (48).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-8,10,11,13,14,17-19, 23, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,786,918 to Krivoruchko et al. ('918) in view of US Patent No. 6,129,700 to Fitz.

'918 discloses a catheter that includes an outer shaft (26), inner shaft (24), fluid channel (68A-H), admission port (shown in Figures 3 and 15), stent (28) mounted on the distal region, and a spacer (62) comprising a plurality of "splines" disposed in the fluid channel. The spacer (62) can best be seen in cross-section in Figure 5 and is substantially similar to the spacer shown in Figure 5 of the application. Figure 2

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illustrates that the spacer (62) extends a majority of the length of the catheter shafts (24,26). The admission port that extends through the sidewall of the handle in Figures 3 and 15 (column 6, lines 12-20) is similar to admission port (42) at the proximal end of the shaft disclosed in applicant's specification. The port is in communication with the fluid channel, as Krivoruchko explains that saline may be delivered to the lumen (column 6, lines 12-13), so the structure of the admission port disclosed by Krivoruchko is considered to meet the claim requirements. '918 discloses that the inner and outer shafts are slidable relative to one another (column 3, lines 35-37). As shown in Figure 2, a guide wire (82) may be disposed in the lumen of the inner shaft (24) (column 6, lines 13-14). The stent (28) is self-expanding and deployed by retraction of the outer shaft (26).

Krivoruchko fails to include a discharge opening in the wall of the outer shaft near the stent mounting location. Fitz discloses another stent delivery catheter and teaches that a discharge opening (54) should be formed through the wall of the outer shaft near the stent mounting location. Fitz teaches that the discharge opening at the distal end of the outer tubular member (22) allows fluids, such as contrast media, to flow from the fluid channel (24) to a patient's lumen during stent deployment (column 4, lines 25-35). There is a plurality of such apertures (54), and the apertures (54) are located on the portion of the outer tubular member (22) covering the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a discharge opening at the distal end of the outer shaft of the Krivoruchko device, as Fitz teaches that this allows therapeutic fluids to be delivered to a patient's lumen during stent deployment.

Regarding claims 17 and 18, the spacer is considered to have a surface that is *capable of* being thermally bonded to another surface. No other structural characteristics are required by these claims.

3. Claims 25,26,28,29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,129,700 to Fitz in view of Blaeser et al.

As clearly illustrated in Figure 5 of Fitz, the device includes an outer tubular member (22), inner tubular member (16), fluid channel (24) between the outer and inner tubular members, and stent (14) mounted on the distal end of the inner tubular member (16). It is inherent from the disclosure that a port in communication with the fluid channel (24) is included to provide fluid to the channel (24).

A discharge opening (54), or “fluid exchange aperture”, at the distal end of the outer tubular member (22) allows fluid to flow from the fluid channel (24) to a patient’s lumen (column 4, lines 25-35). There is a plurality of such apertures (54), and the apertures (54) are located on the portion of the outer tubular member (22) covering the stent. The stent is self-expanding (column 3, line 41) and is deployed by retracting the outer tubular member (22) (column 4, line 64), as shown in Figure 7. The inner tubular member (16) is hollow and defines a guide wire lumen (18).

Fitz fails to include fluid exchange apertures at both the proximal and distal ends of the stent. As discussed above, Blaeser shows that it is known in the art to provide apertures over the length of an outer sheath that covers a stent mounting region. Some of the apertures may be located proximal or distal to the “stent mounting location”, since the sheath (28) extends past both ends of the stent (48). Blaeser teaches that the apertures can enhance flexibility (column 6, lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention

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was made to include apertures proximal and distal the stent mounting region of the Fitz device, as Blaeser teaches that an array of apertures in a retractable sheath of a stent delivery device can enhance flexibility. Further it has been held that a mere duplication of a part of a device involves only routine skill in the art.

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of Blaeser, and further in view of US Patent No. 5,005,584 to Little.

The modified Fitz includes all the limitations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the modified Fitz device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Little guide wire for the guide wire of the modified Fitz device, as this produces a combination that is capable of measuring fluid pressure within a passageway. This combination would be provide the operator with the capability of detecting defects in the body passageway.

Response to Arguments

5. Applicant's arguments filed 12/1/05 have been fully considered but they are not persuasive. Applicant argues that Blaeser does not include holes in the sheath proximal and distal to the stent. The "stent mounting location" is considered to be the portion covered by the stent. As shown in Figures 1 and 2, the sheath extends beyond both ends of the stent. Figures 4 and 5 show holes in the sheath extending the length of the sheath. Since the holes may be located proximal and distal of the stent, Blaeser is considered to meet the limitations of claim 32.

6. Applicant's arguments with respect to the 102 rejection under Krivoruchko et al. have been considered but are moot in view of the new ground(s) of rejection.

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7. Applicant's arguments filed 12/1/05 have been fully considered but they are not persuasive. Applicant argues that the combination of Fitz and Blaeser does not meet the requirements of claims 25,26, 28,29, and 31 because Blaeser does not include discharge openings at both ends of the stent. Some of the apertures may be located proximal or distal to the "stent mounting location", since the sheath (28) extends past both ends of the stent (48). The apertures are proximal and distal the stent, regardless of any other structure the delivery device may include.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
2/9/06


Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER